

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference H1-107PCT5	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP00/05063	International filing date (day/month/year) 28 July 2000 (28.07.00)	Priority date (day/month/year) 29 July 1999 (29.07.99)
International Patent Classification (IPC) or national classification and IPC C12N 15/12, C07K 14/47, C12N 5/10, 1/21, 1/19, C12P 21/02, C07K 16/18, G01N 33/53, 33/577, C12Q 1/02, 1/68		
Applicant HELIX RESEARCH INSTITUTE		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>8</u> sheets, including this cover sheet. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of _____ sheets.
3. This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input checked="" type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input checked="" type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input checked="" type="checkbox"/> Certain observations on the international application

Date of submission of the demand 25 January 2001 (25.01.01)	Date of completion of this report 24 July 2001 (24.07.2001)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

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I. Basis of the report

1. With regard to the **elements** of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the drawings:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

See supplemental sheet for continuation of Box IV. 3.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-13

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: IV. 3.

The inventions set forth in Claims 1-13 can be classified into 75 groups of inventions - groups of inventions (the relevant parts of Claims 1-13) relating to DNA including nucleotide sequences given in SEQ ID NO: 1, 3, 5, 7, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 71, 73, 75, 77, 79, 81, 83, 85, 87, 89, 91, 93, 95, 97, 99, 101, 103, 105, 107, 109, 111, 113, 115, 117, 119, 121, 123, 125, 127, 129, 130, 132, 134, 136, 138, 140, 142, 144, 146 and 148 - and said groups of inventions do not constitute a group of invention so linked as to form a single general inventive concept.

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PCT/JP 00/05063**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	10-13	YES
	Claims	1-9	NO
Inventive step (IS)	Claims	10-13	YES
	Claims	1-9	NO
Industrial applicability (IA)	Claims	1-13	YES
	Claims		NO

2. Citations and explanations

Document 1: WO, 98/37094, A2 (Genetics Inst. Inc.), 27
August 1998 (27.08.98)

Claims 1-9 are not novel and do not involve an inventive step in the light of Document 1 cited in the international search report. Document 1 discloses a polynucleotide which hybridizes under stringent conditions with a polynucleotide including the nucleotide sequence given in SEQ ID NO:1, a protein coded by said polynucleotide, a vector including the aforementioned polynucleotide, transformed cells including aforementioned polynucleotide, a process for producing the aforementioned protein by culturing said transformants, polynucleotides having a length of at least 15 bases from the nucleotide sequence of the aforementioned polynucleotide, and an antibody against the aforementioned protein.

The inventions set forth in Claims 10-13 are not disclosed in the documents cited in the international search report, and are novel and involve an inventive step. Document 1 does not disclose an association between the polynucleotide which hybridizes under stringent conditions with a polynucleotide including the nucleotide sequence given in SEQ ID NO:1 and the presence of stomach cancer, and this association could not be easily deduced

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by a person skilled in the art from the disclosure in
Document 1.

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VI. Certain documents cited

1. Certain published documents (Rule 70.10)

<u>Application No. Patent No.</u>	<u>Publication date (day/month/year)</u>	<u>Filing date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
WO,99/55858,A2 [P,X]	04 November 1999 (04.11.1999)	19 April 1999 (19.04.1999)	28 April 1998 (28.04.1998)

2. Non-written disclosures (Rule 70.9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure (day/month/year)</u>	<u>Date of written disclosure referring to non-written disclosure (day/month/year)</u>
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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 11 is not fully supported by the description.